BY DENISE MYSHKO

REGULATIONS

THE SAFETY FIRST ERA

In the post-REMS world, pharmaceutical companies have an opportunity to differentiate themselves and positively impact healthcare delivery.

The classwide requirement for Risk Evaluation and Mitigation Strategies (REMS) for opioid products is likely to have a profound impact on the pharmaceutical industry and healthcare. While most REMS involve only a medication guide — which is likely to have little impact on the prescribing process — experts say the Food and Drug Administration's classwide requirement for opioids opens new opportunities for companies.

"There is no doubt that more extensive REMS programs with more comprehensive 'elements to assure safe use,' such as registries, will definitely complicate — and in some cases potentially dissuade — prescribing and thus may limit the potential of many brands," says Dan Bobear, executive VP, managing director of client service, at Palio. "In the case of a classwide REMS mandate, such as in opioids, healthcare providers will adjust and life will go on. I think it is really important to embrace the REMS mandate as, for some drug classes, it will most definitely have a positive impact on public health."

Karla Anderson, managing director, pharmaceuticals and life-sciences advisory services group, at PricewaterhouseCoopers, says there is an opportunity to design REMS programs in a manner that tightly integrates the REMS requirements with the overall customer interaction model and leverages technology to make the REMS interventions as simple and intuitive as possible.

Dan Bobear
Palio

"While a classwide REMS will be an initial shock, it is the only practical way to apply the mandate in the opioid category."

"Companies need to take a multidisciplinary approach to REMS design to make sure the program design and assessments are in alignment with the overall efforts of the commercial teams while meeting the regulatory and safety requirements as well as ensuring the required data are captured effectively across the REMS stakeholders universe," she says.

With a well-thought-out strategy and successful implementation of REMS, companies can enhance the prescribing process, says Scott Treiber, Ph.D., executive VP, clinical development solutions, at inVentiv Clinical Solutions.

"Drug/biologic developers need to look outside to partners that have the cross-functional expertise — safety, market analysis, therapeutic experience, etc. — to ensure that REMS programs work to their advantage," he says.

The pharmaceutical industry has traditionally served as an important step in the supply chain, says Jeff Fetterman, president of ParagonRx.

"The regulatory requirements of REMS pull pharma companies into a closer partnership with healthcare professionals in the delivery of care by helping to assure certain medications are used appropriately: the right medication, the right patient, the right dose, the right administration, and then monitoring the outcomes," he says. "This is new ground for pharma companies and it will require new scientific approaches, new staffing, and new capabilities to implement effectively."

OPIOID SAFETY

Earlier this year, the FDA strengthened the required risk minimization and action plans for opioids, in addition to other high-risk drugs. These drugs will be required to have a REMS to ensure that the benefits of the drugs continue to outweigh the risks.

The affected opioid drugs include brand name and generic products and are formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone.

Mr. Fetterman says the burden associated with this program has yet to be determined.

> The opioids market is set to grow from $9.6 billion in 2008 to $11.9 billion in 2018 across the seven major markets.
>
> DATAMONITOR

"At a minimum, it is a significant resource burden for the affected manufacturers that must collaborate to design the program," he says. "Depending on the design of the program, it could require a significant administrative burden on behalf of healthcare professionals and patients. Any design of this scale and complexity is likely to have unintended consequences unless precise, deliberate steps are taken."

Mr. Fetterman says because millions of patients and several hundred thousand prescribers use these long-acting opioid products, there is a need for shared systems, and because the FDA will require all products and manufacturers to collaboratively design and operate a single shared system, this will be a program of unprecedented complexity.

"The only precedent for a shared-system risk mitigation program is the iPLEDGE

PRESCRIPTION DRUG ABUSE AND MISUSE

- The nonmedical use or abuse of prescription drugs is a serious and growing public health problem in this country.
- The elderly are among those most vulnerable to prescription drug abuse or misuse because they are prescribed more medications than their younger counterparts.
- An estimated 48 million people (ages 12 and older) have used prescription drugs for nonmedical reasons in their lifetimes. This represents about 20% of the U.S. population.
- 9.3% of 12th-graders surveyed in 2004 reported using Vicodin without a prescription in the previous year, and 5.0% reported using OxyContin, making these medications among the most commonly abused prescription drugs by adolescents.

Source: National Institute on Drug Abuse.
For more information, visit nida.nih.gov.

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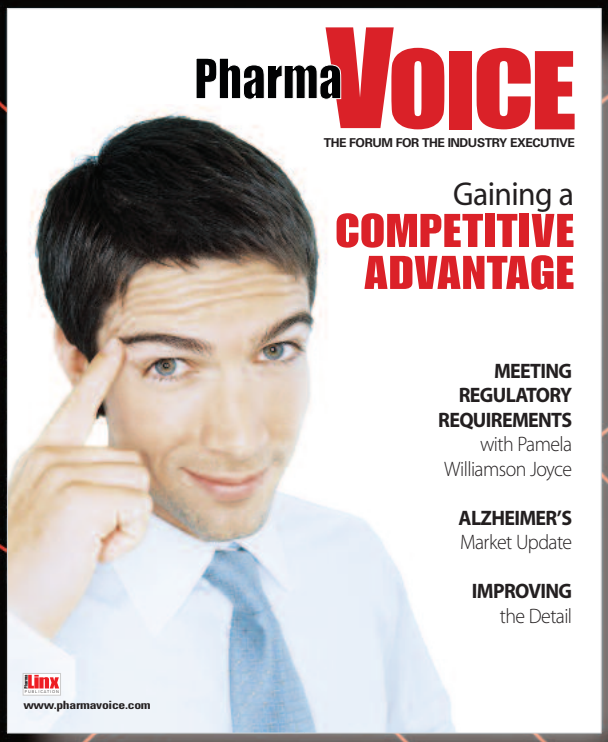

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Jeff Fetterman
ParagonRx

"This is an opportunity for nimble organizations to differentiate themselves and their products in the post-REMS world."

Nayan Nanavati
Parexel

"It is very likely that the formal risk-reduction plan proposed by FDA on opioids will increase the administrative and regulatory burden on prescribing physicians."

pro310%gram for isotretinoin, which included four manufacturers with 15,000 prescribers and 400,000 patients," he adds.

Mr. Bobear says a classwide REMS requirement for long-acting opioids pre-supposes that all compounds share the same features and that only a REMS program can help to ensure that the benefits of the drugs continue to outweigh the risks.

"This approach has significant implications for the practice of pain medicine and may actually provide more legal clarity for the prescribing of opioids than in the past," he says. "The opioid class is very large, and these products are critically important to millions of patients living with chronic and acute pain. If each opioid had an extensive and customized REMS initiative, it would place a major burden on the healthcare system as multiple contacts in the system would have to learn the nuances of each REMS program."

According to Nayan Nanavati, VP and general manager, peri- and postapproval research, and worldwide head of pharmacovigilance at Parexel International, it is very likely that the formal risk-reduction plan proposed by the FDA on opioids will increase the administrative and regulatory burden on prescribing physicians.

"As a consequence, we believe that physicians will take a more conservative approach in treating their patients with pain killers, including identifying other treatment options or stopping the prescribing of these drugs altogether," he says. "With this REMS initiative, physicians must register first with the Drug Enforcement Agency, and as more regulatory guidelines are imposed it is expected that their practices will be severely scrutinized and impacted by more administrative and regulatory burdens."

An unintended consequence of REMS for opioids, Mr. Nanavati says, may very well be that physicians are expected to teach the law to patients and pharmacists.

"This is a dangerous position," he says. "The problem related to opioids is not limited to what is being prescribed and how. While REMS-related enforcement should improve the side effects of opioid prescriptions, it does not fully address the current easy access to these non-prescribed drugs."

REMS GOING FORWARD

Mr. Nanavati says ultimately biopharmaceutical companies will need to be fully versed in evolving developments through this opioid-class REMS initiative.

"Compliance adherence is critical to be successful in the marketplace," he says. "Additionally, ensuring that the plan put into effect is working in the manner it is intended, as well as ongoing assessment of the plan, will be equally critical."

Ms. Anderson says initiatives such as the proposed and now delayed classwide REMS, will require that multiple manufacturers establish new ways of working together to gain consensus on development and operational issues.

"The concept of a REMS program that includes 25 manufacturers will clearly change the way the market views REMS and the operational model to manage all the interactions from an aggregate and company-specific perspective," she says. "If the opioid or similar classwide initiatives move forward, it will accelerate the move toward REMS standardization from an operational perspective."

Dr. Scott Treiber
inVentiv Clinical Solutions

"A well-thought-out strategy and successful implementation of REMS can enhance the prescribing process."

She says there is already market momentum to create standards across REMS programs to prevent prescribers and providers, including pharmacies and wholesalers, from having to administer highly variable REMS programs.

"The classwide approach levels the playing field relative to market barriers related to use of a drug, and as a result the multiple manufacturers will be incentivized to work toward a common customer interaction model that allows the appropriate drug to be selected by prescribers without a concern that the REMS program makes it too cumbersome." ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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Who will be the 2010 HBA

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» REGULATIONS

Sound Bites From The Field

PHARMAVOICE ASKED INDUSTRY EXPERTS TO IDENTIFY SOME OF THE TRENDS THAT ARE IMPACTING REGULATIONS AROUND THE WORLD.

JAN-ANDERS KARLSSON, PH.D., is CEO of S*BIO Pte Ltd., which is focused on the discovery and clinical development of novel targeted small molecule drugs for the treatment of cancer. For more information, visit sbio.com.

"Although standards are becoming more uniform, different regions in the world will require slightly different approaches to development, regulatory approval, and marketing for success. The emphasis is on unmet medical needs. These unmet needs, however, have some regional specificity, providing further opportunities to regional biotech companies."

ILYSSA LEVINS is President and Founder, Center for Communication Compliance (CCC), a centralized resource, training, and certification portal designed to support and enhance risk communication and regulatory compliance. For more information, visit communicationcompliance.com.

"Strict regulatory compliance will continue as priority No. 1 for the pharmaceutical industry. A reinforced FDA means more thorough regulatory scrutiny, more required REMS programs, and more warning letters for drug and device companies. Huge financial incentives for whistleblowers will continue the steady stream of federal and state indictments for off-label promotion. Settlements will continue to become more costly and their exhaustive Corporate Integrity Agreements (CIAs) will hold increasingly more stakeholders accountable. Furthermore, the industry's credibility will continue to suffer if pharma companies are in the headlines for breaking the law.

These challenges require drug and device companies to break down internal silos across the entire organization. Collaboration unifies company employees around a culture of compliance and underscores the need for excellence in risk mitigation and communication. Promotional agencies will play a greater role in maintaining regulatory compliance through investments in training and certification as a requirement for doing business. Through partnerships, internal and external stakeholders will be able to engage in more effective planning and enjoy sustainable process improvements, lowered operating costs, improved market share, and increased margins."

JAMES R. WESTON is Senior VP of Talaris Advisors LLC, which provides solutions for drug, diagnostic, and device development worldwide bringing significant flexibility and efficiency to clients through turnkey management solutions. For more information, visit talarisadvisors.com.

"I believe that throughout the next 10 years there will be increased harmonization of the worldwide regulatory authorities leading to more efficient, effective, and timely drug development. Each country will still be responsible for its individual regulatory administration, but I believe that there will be a common set of criteria, which will both simplify and unify the drug approval process in major world markets, making drugs more accessible and affordable."

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